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Answer given by Ms Kyriakides
on behalf of the European Commission
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The Commission is planning to adopt a pharmaceutical strategy by the end of 2020, which aims to address the life cycle of medicines from research and development to authorisation, including patient access and how to put scientific and technological advances into practice. A public consultation process is ongoing until 15 September 2020[1].

The existing EU legal framework for pharmaceuticals[2] can be applied for the approval of marketing authorisations for medicinal products including nanomedicines and nanosimilars and there are already several medicines approved in the EU applying nanotechnology (including nanomaterials[3]). While there is no definition for 'nanomedicines', efforts are being made to better understand the specific properties of nanomaterials in medicines and to continuously improve the available scientific guidance. The European Medicines Agency's scientific guidelines on nanomedicines help medicine developers prepare marketing authorisation applications for human medicines[4]. Currently, the Commission does not consider that there is a need to revise the pharmaceutical legislation with respect to nanomedicines. One of the pillars of the pharmaceutical strategy will be enabling sustainable innovation contributing to a "future proof" framework, and in this context stakeholders' views on regulatory issues related to nanomedicines will be taken into account.

Finally, the new EU regulation on medical devices[5] contains specific requirements on devices incorporating or consisting of nanomaterials.

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines
[2] Directive 2001/83/EC and Regulation (EC) No 726/2004
[3] The EU adopted a definition of a nanomaterial in 2011 (Recommendation on the definition of a nanomaterial 2011/696/EU)
[4] https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/multidisciplinary/multidisciplinary-nanomedicines
[5] Regulation (EU) 2017/745, amended Regulation 2020/561, Regulation (EU) 2017/746